



## Package leaflet: information for the user

# Tropicamide 1% w/v eye drops, solution, single-dose container

Tropicamide

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

### What is in this leaflet

1. What this medicine is and what it is used for
2. What you need to know before you use this medicine
3. How to use this medicine
4. Possible side effects
5. How to store this medicine
6. Contents of the pack and other information

## 1 What this medicine is and what it is used for

Tropicamide contains a mydriatic and cycloplegic agent. It is used to enlarge the pupil of your eye and temporarily paralyse the lens. Your doctor or eye specialist may use it to examine your eye.

## 2 What you need to know before you use this medicine

### Do not use this medicine:

- if you are allergic to the active substance (tropicamide) or any of the other ingredients (listed in section 6).
- if you have history of closed angle glaucoma with your eyes likely to develop sudden increased internal pressure when the pupil is enlarged.

### Warnings and precautions

Talk to your doctor, pharmacist or nurse before using tropicamide.

Use of this product may cause:

- Increase in the pressure of your eye. You should have your eye pressure checked before initiation of therapy, especially in the elderly.

### Take special care

Ask yourself the following questions:

- Is this product to be used in a small child?
- Are your eyes red or inflamed?

If the answer to any of these questions is yes, tell your doctor or eye specialist.

### Children

Consult your doctor for advice as serious adverse reactions may occur with the use of this product.

### Other medicines and Tropicamide

Tell your doctor, pharmacist or nurse if you are using, have recently used or might use any other medicines.

### Pregnancy, breastfeeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before taking this medicine.

### Contact lenses

Your doctor will ask you to remove your contact lenses prior to the administration of the drops. There is no information on the effect of this product on contact lenses. Therefore, do not wear your contact lenses until the effects of the drops have completely worn off.

### Driving and using machines

Some people find bright light (such as daylight) uncomfortable for a few hours after receiving Tropicamide. This may make it difficult for you to drive. As with all eye drops, your vision may be blurred after putting the drops in. Wait until your vision is clear before driving or using machines.

## 3 How to use this medicine

Always use this medicine exactly as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The drops are for single use only and provided in single use units, to treat both eyes if necessary. Once opened, use immediately. Discard any unused portion.

### The recommended dose is:

- The normal adult dose is 1 drop followed by a second drop after an interval of 5 minutes. A further 1 drop may be instilled after 30 minutes, if required.
- The dose for children will be decided by the doctor or eye specialist.

### Method of administration

Make sure you follow these instructions carefully:

1. Wash your hands.
2. Use a mirror, this will help you to see what you are doing.
3. Carefully dry your eyes using a tissue, and twist off the cap from the body of the unit.
4. Pull your lower eyelid down gently, and then carefully place 1 or 2 drops inside your lower eyelid.
5. Close your eye and blink a few times to make sure your eye is covered by the liquid.
6. Close the eyelids. It is advisable to press gently on the inner corner of your eyelid for 3 minutes. This will help stop the solution draining into your nose and throat. This is especially advisable in children, the elderly and population at risk.
7. Repeat steps 4, 5 and 6 for the other eye, if necessary, then throw away the unit, even if some solution remains.

### If you use more Tropicamide than you should

An overdose is very unlikely to occur. If you suddenly feel unwell after receiving the drops, tell your doctor or eye specialist or contact your nearest emergency department immediately.

## 4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects may occur:

- temporary stinging and blurred vision. This will gradually wear off.
- dry mouth. This is caused by the active substance being absorbed through the tear duct and causing a common effect for this type of medicine. This effect should wear off within a couple of hours.

If any of the side effects gets serious, please seek immediate medical attention. If you notice any side effects not listed in this leaflet, please tell your doctor, pharmacist or nurse.

### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme (Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store). By reporting side effects, you can help provide more information on the safety of this medicine.

## 5 How to store this medicine

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the overwrap of each unit and on the carton after the letters "EXP". The expiry date refers to the last day of that month.

Store below 25°C.

Store ampoules in the original pouch. Once open, the pouch should be used or discarded after 14 days. Do not freeze.

The drops are for single use only and provided in single use units, to treat both eyes if necessary. Once opened, use immediately. Discard any unused portion.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

## 6 Contents of the pack and other information

### What this medicine contains

- The active ingredient is tropicamide. Each unit contains approximately 0.5ml eye drops solution of tropicamide 1% w/v (5mg).
- The other ingredients are hydrochloric acid (for pH adjustment) and purified water.

This medicine does not contain a preservative as it is a sterile single use unit.

### What this medicine looks like and contents of the pack

This medicine is a clear, colourless solution. Each aluminium pouch contains 5 low density polyethylene single-dose containers containing 0.5ml of solution.

### Pack sizes:

20 x 0.5ml (4 pouches with 5 single-dose containers)

### Marketing Authorisation Holder and Manufacturer

#### Marketing Authorisation Holder

Aspire Pharma Limited, Unit 4, Rotherbrook Court  
Bedford Road, Petersfield, Hampshire, GU32 3QG, UK

#### Manufacturer

UNOLAB MANUFACTURING S.L  
Avenida Rita Levi Montalcini N°23  
28906 Getafe, Madrid, Spain

### Blind or partially sighted?

### Is this leaflet hard to see or read?

Call 01730 231148 to obtain the leaflet in a format suitable

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